

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Southwest Import District 4040 N. Central Expy, Suite 300 Dallas, Texas, 75204

Telephone: 214-253-5330

FAX: 214-253-5316

January 28, 2002

Ref: 2002-SWID-WL-02 Entry # F62-1001874-4

WARNING LETTER

VIA Federal Express

Mr. Dennis Mussell, President Chicken of the Sea International 4510 Executive Drive, Suite 300 San Diego, CA 92121-3029

Dear Mr. Mussell:

On January 25, 2001, the Food and Drug Administration (FDA) attempted to examine a shipment of cartons of Premium Light Tuna in Pouches consigned to your firm from Thai Union Frozen Products Public Co. Ltd., Bangkok, Thailand. FDA confirmed that this lot of tuna has been completely distributed into U.S. commerce without a proper FDA release.

This shipment of tuna was sampled on May 30, 2001 and examined by FDA for decomposition. The lot was found to be violative for decomposition and was detained on June 14, 2001. Following receipt of the notice of detention, Chicken of the Sea requested and received an extension of time to prepare a reconditioning request for the entry. The request was initially denied. The latest revision received from Chicken of the Sea was approved on December 3, 2001. On December 11, 2001, FDA received a fax of a letter from Chicken of the Sea providing information that the entire shipment may no longer be available for sampling and examination.

On January 25, 2002, FDA attempted to examine this entry of tuna. This shipment was not available for FDA to examine and was distributed out of Shippers Warehouse, Dallas, Texas with shipments made between June 5, 2001 and November 27, 2001.

Distribution from this shipment of tuna began 5 days following the FDA sample collection on May 30, 2001. It is a violation of 21 USC § 381(a) and Title 21 of the Code of Federal Regulations Section 1.90 that requires the importer to hold an imported article and not distribute it pending receipt of the results of FDA examination of the sample. Shipments of this lot were distributed even after the FDA issued a notice of detention indicating adulteration of this tuna due to the presence of decomposition. It is a prohibited act (21 USC § 331(a)) to introduce into interstate commerce a food that is adulterated according to 21 USC § 342(a)(3) "if it consists in whole or in part of any

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filthy, putrid, or decomposed substance". Failure to promptly correct this situation may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of Customs, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

In addition, we have requested that Customs demand redelivery of this shipment. Failure to redeliver the missing product to Customs' custody may result in an assessment of liquidated damages at a later date.

Within 15 working days of receipt of this letter notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence and any attempts to retrieve any of this violative product in U.S commerce. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your response should be addressed to Deborah M. Floyd, Compliance Officer, at the address noted in the letterhead.

Sincerely,

Robert J. Deininger District Director

Enclosure: FDA Notice of Refusal 1-28-02

cc: Mr. Harry Katsaros, Owner TWIN Customs Brokerage, Inc. 755 Port America Place, Suite 343 Grapevine, TX 76051

> Mr. Darby Strickland, Owner/President Shipper's Warehouse Inc. 8901 Forney Road, Dallas, TX 75227

Mr. Paul Rimmer, Port Director U.S. Customs Service P.O. Box 619050 Dallas, Texas 75261